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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,445	07/23/2003	Timothy Lovenberg	JJPR-0032	1837

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,445	LOVENBERG ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 – 4, 6, 7, 9, 10, 12, 13, and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *6 and 7* is/are allowed.

6)☒ Claim(s) *1 - 3, 9, 10, 12, 13, and 16* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and remarks filed 11 March 2005 have been entered. Claims 5, 8, and 11 have been cancelled by applicant, claims 1, 4, 7, 10, and 13 have been amended. No new claims have been presented. Claims 1 – 4, 6, 7, 9, 10, 12, 13, and 16 are pending and under examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1 – 4, 6, 7, 9, 10, 12, 13, and 16 of this application. The claims are drawn to mouse histamine H4 receptor, which has SEQ ID NO:8, and which is encoded by the nucleic acid with SEQ ID NO:5. The provisional application, 60/208,260 discloses the human sequence but not the mouse sequence. Therefore the priority date for all pending claims is set at the filing date of the instant application, 22 February 2001.

Information Disclosure Statement

4. The information disclosure statement filed 8 October 2004 was not considered by the examiner in the previous office action. It was filed before the first action on the merits and has been considered. PTO-1449 is attached.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title is drawn to mammalian H4 receptors, but the claims are all drawn to mouse H4 receptors

The following title is suggested: DNA encoding mouse histamine receptor of the H4 subtype.

Claim Objections

6. Claims 1, 6, 9, and 16 are objected to because of the following informalities: the claims recite "a mammalian histamine H4 receptor" but are drawn to a *mouse* histamine H4 receptor. This objection could be overcome by amending the claims to read "a mouse histamine H4

receptor" or "a murine histamine H4 receptor". Furthermore, claim 1 recites "a polynucleotide encoding"; the term "a polynucleotide *sequence* encoding" would clarify the claim.

Appropriate correction is required.

Withdrawn Objections and Rejections

7. The following objections and rejections made in the previous office action are hereby withdrawn:

Objections to the drawings, specification, and claims. Applicant has made the changes suggested by the examiner.

Rejections under 35 USC § 102 (e). Applicant has canceled parts (c) and (d) of claim 1, rendering the rejection moot.

The rejection of claim 5 under 35 USC § 112, first paragraph, for failing the enablement requirement. Applicant has canceled claim 5.

The rejection of claims 1 – 3, 5, and 12 under 35 USC § 112, first paragraph, for failing to provide a complete written description. Applicant has canceled the problematic sections of claim 1.

The rejections of claims 5, 8, and 11 under 35 USC § 112, first paragraph, for failing to provide a complete written description. Applicant has canceled all rejected claims.

The rejections under 35 USC § 112, second paragraph. Applicant has canceled all rejected claims.

Rejections Maintained

8. Claims 1 – 3 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to isolated nucleic acids that encode mammalian histamine receptors. Dependent claims are drawn to specific nucleic acids (claims 2 and 3) and protein encoded by said nucleic acid. The preamble of claim 1 requires that the nucleic acids encode histamine H4 receptors. It is acknowledged that the nucleic acid of part (a) of claim 1 encodes a histamine H4 receptor. However, the nucleic acid of part (b) of claim 1 is complementary to a nucleic of (a) and therefore will not encode a histamine H4 receptor.

In the remarks filed 11 March 2005, applicant argues that the claim is fully enabled, since one of ordinary skill in the art would know how to make a nucleic acid complementary to any given nucleic acid. Applicant's arguments have been fully considered but they are not persuasive.

Applicant has not explicitly defined the term "nucleic acid" but has defined "polynucleotide" to include single-stranded DNA and RNA (specification, p. 16, lines 10 – 15). Alberts et al. (1994. Molecular Biology of the Cell, Third Edition, p. 4) provide a definition for "polynucleotides" which clearly indicates the term to be synonymous with "nucleic acid". Therefore the examiner considers that the definition provided on p. 16 of the specification applies to both terms. An isolated nucleic acid can be a single-stranded DNA or RNA. The preamble of the claim requires that the nucleic acid encode a histamine H4 receptor, but as stated both in the previous office action and herein, nucleic acids complementary to an H4-encoding sequence do not themselves encode an H4 receptor. MPEP § 2111.02 states that the determination as to whether the preamble limits a claim must be made on a case-by-case basis. In the instant case, the examiner has concluded that the preamble *requires* that all claimed nucleic acids must encode an H4 receptor.

New Rejections

Claim Rejections - 35 USC § 112

9. Claims 9, 10, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated host cells, does not reasonably provide enablement for cells residing in a host organism, including humans, which have been infected by a retrovirus containing the claimed nucleic acid, as one would reasonably expect in gene therapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8

USPQ2d 1400, 1404 (FED. Cir. 1988). The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

The specification speaks of gene therapy (p. 30, lines 1 – 23). While the specification is enabling for contact with isolated cells, and the transformation or transfection of isolated cells to express mouse H4 nucleic acid or protein, via nucleic acid and vector delivery, the specification fails to teach suitable administration such that gene therapy methods could be carried out. Those skilled in the art recognize that such technology is currently beyond scope. In particular, Marshall "Gene Therapy's Growing Pains". Science, Vol. 269 (1995), pp. 1050-1055, and Verma, I. M., et al. "Gene therapy-promises, problems, and prospects". Nature, Vol. 389 (September 1997), pp. 239-242, and Orkin et al. (1995) "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy" all denote significant troubles associated with transgenic and in vivo gene therapy approaches to the assessment of in vivo methods and treatments.

The specification fails to provide any exemplary evidence for conducting such screening approaches in vivo, using either transgenic or gene therapy treated cells within an organism. Since the scope of "recombinant host cell" is deemed to be so inclusive as provided by direct guidance within the specification, the scope of enablement provided by the specification is not commensurate in scope with the claims.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Amendment to "isolated" cells is recommended.

10. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites the term "substantially purified" which is not explicitly defined in the specification. A skilled artisan would not know when a molecule becomes "substantially purified" and thus could not determine the metes and bounds of this claim. Amendment to "isolated" is recommended.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 – 3 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene random primers, 1991 catalog, p. 66.

Stratagene teaches the use of random 9-mers capable of hybridizing with all possible gene sequences. The random primers meet the limitations of part (b) of claim 1 because the primers are a complement to nucleic acids which encode SEQ ID NO:8 and are able to bind under stringent hybridization conditions as the activity of extension exemplified is dependent upon hybridization of the random primer sequences. As noted in the catalog the primers and included reagents are capable of generation 500-1000 nucleotide segment primer copies. Thus, the reference teachings anticipate the claimed invention. This rejection could be overcome by amending the claim to recite "a polynucleotide sequence which is the full-length complement of the polynucleotide of (a)."

Conclusion

13. Claims 6 and 7 are allowed because they are free of the prior art, and have utility; they can be used to purify histamine as shown in Example 11.

Claims 1 – 3, 9, 10, 12, 13, and 16 are rejected.

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.
April 20, 2005

SHARON TURNER, PH.D.
PRIMARY EXAMINER
4-20-05